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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/092,296	06/05/1998	PATRICIA BILLING-MEDEL	6104.US.01	5920

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/07/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/092,296

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-10,13,35-37 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-37,39-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

***Request for Continued Examination***

The request filed on February 10, 2003 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/092,296 is acceptable and a RCE has been established. An action on the RCE follows.

Claim 38 was cancelled.

Claims 7-10, 13, 35-37, and 39-45 are pending.

Claims 7-10, and 13 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 35-37, and 39-45 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained:**

Claims 35-37, and 39-45 remain rejected under 35 U.S.C. 101 for the reasons of record in Paper No. 16, pages 6-9.

Applicants argue (Paper No. 33, page 6) that contrary to the Examiner's statement made in Paper No. 26 (i.e., that "there is no evidence to suggest that the claimed polynucleotides are overexpressed in lung tissue"), the examples on pages 57-58 of the specification show that EST's corresponding to the consensus sequence of LS147 were found in 15/42 (35.7%) of lung tissues.

This argument has been considered but is not found persuasive because it appears that Applicants have taken the previous comment out of context. While there may be overexpression of lung-specific polynucleotides corresponding to LS147, said overexpression is not indicative of a diseased state (Paper No. 26, page 4, 2<sup>nd</sup> full paragraph). Therefore, such expression does not represent a substantial or real-world utility.

Applicants further reiterate their arguments that detection of LS147 outside of the lung is diagnostically useful because it serves as an indicator that the host (lung) is in a diseased state. Applicants further equivalent their novel marker to known diagnostically useful markers such as PSA and CEA. Applicants argue that these known markers are still recognized as useful in the diagnosis of disease of their primary tissue of origin. These arguments have been considered but are not found persuasive for the reasons of record and for the reasons set forth below.

If a molecule, such as those corresponding to the expression patterns of LS147 are to be used as a surrogate for a diseased state, *some diseased state must be identified* in some way with the molecule. In other words, there must be some expression pattern or diagnostic setting that would permit the claimed polynucleotide to be used in such a manner. Further, many nucleic acids may be considered to have tissue-specific expression; however, for utility purposes, one needs to know, e.g., that the claimed polynucleotide is present only in cancer tissue or only in specific diseased states to the *exclusion* of the corresponding normal tissue. Hence, the comparison to known disease markers such as PSA or CEA, is beyond the scope of applicant's disclosure because applicants have not shown that the claimed polynucleotide is present only in cancer tissue or only in specific diseased states to the *exclusion* of the corresponding normal tissue.

Applicant further point to the submitted declaration (Paper No. 34) of Dr. Paula Friedman wherein the specificity of LS147 closely resembles the tissue specificity of PSA and CEA. These arguments and the declaration have been carefully considered but are not found persuasive. While the nucleic acids associated with LS147 may closely parallel other known disease markers in so far as they are tissue-specific, the instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. (In this case, beyond their tissue-specific expression, PSA and CEA are well known in the art as tumor-associated antigens, which contrast with LS147- only disclosed as a tissue-specific marker in lung tissues.) The court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed “real world” utility. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where *specific* benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is

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not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 35-37, and 39-45 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicants reiterate their arguments as set forth in response to the utility rejection. Thus, for the reasons of record and for the reasons set forth above, applicant's arguments have not been found persuasive and the rejection is maintained.

**New Rejections:**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth below:

Claims 39-40 recite the limitation "wherein the open reading frame" in Claim 39. There is insufficient antecedent basis for this limitation in Claim 39.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40-41, as written, do not sufficiently distinguish over cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
May 1, 2003

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
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